valeritas

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510(k) Summary

DEC 1 2010

K100504

Owner's Name: Valeritas, Inc.
750 Route 202 South, Suite 100
Bridgewater, NJ 08807

Company Contact: Scott Huie
Vice President, Operations
Valeritas, Inc.
800 Boston Turnpike
Shrewsbury, MA 01545
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Date Summary Prepared: 16 November 2010

Trade Name: Valeritas V-Go™ Insulin Delivery Device

Common Name: Disposable Insulin Delivery Device

Classification Name: Pump, Infusion, Insulin/Set, Administration, Intravascular

Classification regulation: Class II: 21 CFR 880.5725
Panel: 80, LZG External Insulin Infusion Pump
FPA Intravascular Administration Set

Substantial Equivalence: The Valeritas V-Go Disposable Insulin Delivery Device is substantially equivalent to the BioValve Insulin Delivery System (BIDS) K050971, cleared by this Center on 16 August 2005

Device Description: The Valeritas V-Go Disposable Insulin Delivery Device is a mechanical (no electronics), self-contained, sterile, patient fillable, single-use disposable insulin infusion device with an integrated stainless steel subcutaneous needle.

It is designed for the subcutaneous infusion of insulin for the management of diabetes mellitus in persons requiring insulin. After filling the V-Go with insulin using the EZ Fill, the device is secured to the patient's skin over the infusion site with an adhesive-backed foam pad, which is attached to the back of the pump. Once activated, the V-Go delivers a continuous infusion of insulin at a fixed rate. The device also allows the user to initiate bolus

injections to supplement their daily basal insulin requirements. Three device models (20, 30 and 40 Units/day) will be available to address the different basal and bolus requirements of each patient. A window in the top of the pump allows the user to see into the reservoir to check the drug and to monitor the progress of the infusion.

Intended Use:

V-Go 20:

The V-Go Disposable Insulin Delivery Device is indicated for continuous subcutaneous infusion of 20 Units of insulin in one 24-hour time period (0.83U/hr) and on-demand bolus dosing in 2-Unit increments (up to 36 Units per one 24-hour time period) in adult patients requiring insulin.

V-Go 30:

The V-Go Disposable Insulin Delivery Device is indicated for continuous subcutaneous infusion of 30 Units of insulin in one 24-hour time period (1.25U/hr) and on-demand bolus dosing in 2-Unit increments (up to 36 Units per one 24-hour time period) in adult patients requiring insulin

V-Go 40:

The V-Go Disposable Insulin Delivery Device is indicated for continuous subcutaneous infusion of 40 Units of insulin in one 24-hour time period (1.67U/hr) and on-demand bolus dosing in 2-Unit increments (up to 36 Units per one 24-hour time period) in adult patients requiring insulin

Technological Characteristics:

The V-Go has two delivery mechanisms, one for basal infusion and one for bolus delivery. Both operate by providing force against a plunger, which is inserted into a cylindrical reservoir filled with high viscosity fluid. This force is directly translated against the rear of the delivery piston at the rear of the insulin reservoir.

The Basal Hydraulic Pump operates by applying a constant force by means of a compressed spring. The spring pushes against a disk inserted internally at the rear of the cylindrical fluid filled basal reservoir, forcing the fluid through a restrictive orifice. This displacement translates into displacement of the medicinal delivery piston, providing a continuous basal infusion. The basal delivery

rate can be varied by the substitution of a different orifice into the device during assembly.

The Bolus Hydraulic Pump operates by applying a force by means of a manually depressed actuator (Bolus Button). Manual actuation allows the displacement of a disk inserted internally at the rear of the cylindrical fluid-filled bolus reservoir in pre-set increments that will displace the volume of fluid and the medicinal delivery piston. The manual actuation requires two steps. First, the user must press the Bolus Release Button. Displacement of the Bolus Release allows the Bolus Button to "pop-out" so that it protrudes slightly from the end of the pump. The user then depresses the Bolus Button, which displaces the Bolus Piston and delivers a pre-set bolus increment. This process is repeated until the desired volume has been delivered or the labeled number of actuations are used up. The Bolus Release Button extends from the pump and locks preventing further use as there are no additional bolus actuations remaining.

Substantial Equivalence:

The Valeritas V-Go is substantially equivalent to the predicate device, the BioValve Insulin Delivery System (BIDS), cleared by this center on 16 August 2005 (K050971). Please note that BioValve contributed the technology to Valeritas in 2006 and that the BioValve device and the Valeritas V-Go device have the same intended use and performance characteristics. The primary differences relate to minor material modifications and an improved method and accessory (EZ Fill) for filling the V-Go pump. In addition, the V -Go comes in three set basal rates (20, 30 and 40 Units/day) and a set incremental bolus (2 Units/actuation, with a maximum of 36 Units/day) whereas the BioValve device had a specified basal range of 14.4 to 57.6 Units/day and bolus increments from 2 to 4 Units.

Non-Clinical Performance Data:

Physical Specifications

Maximum Dimensions:	84 mm x 47 mm x 13 mm
Weight:	20 - 50 grams
Cannula:	Stainless Steel' J' shaped needle (J-needle)
Pump Mechanism:	Spring and Manual Hydraulic Displacement
Interfaces:	Mechanical Buttons

Operational Specifications

Operational Specifications			
Pump Model	**V-Go 20**	**V-Go 30**	**V-Go 40**
Reservoir volume	560 µL (56 IU of insulin)	660 µL (66 IU of insulin)	760 µL (76 IU of insulin)
Basal Rate	8.3 µL/hr (0.6 IU/hr)	12.5 µL/hr (1.2 IU/hr)	16.7 µL/hr (1.8 IU/hr)
Bolus Increments	20 µL (2 IU) 18 Actuations	20 µL (2 IU) 18 Actuations	20 µL (2 IU) 18 Actuations
Nominal Bolus Volume	360 µL (36 IU)	360 µL (36 IU)	360 µL (36 IU)
Basal Volume (24 Hours)	200 µL (20 IU)	300 µL (30 IU)	400 µL (40 IU)
Accuracy	+/- 10%	+/- 10%	+/- 10%

Environmental Specifications - Per AAMI ID26, IPX8

Temperature:	+5 to +37°C
Humidity:	20 - 90%
Water Ingress Protection:	IPX8 (submerged at 1 meter for 24 hours)
Atmospheric Testing:	0-10,000 feet

Biocompatibility – Per ISO 10993-1

Drug and skin contact materials passed all testing per ISO 10993-1. Drug Contact materials were tested and found to be compatible with insulin for the duration of use. Please see the package insert for specific insulin information.

Sterilization and Package Stability

The V-Go and EZ Fill are sterilized using Ethylene Oxide to a Sterility Assurance Level (SAL) of 10^{-6} per ANSI/AAMI ST67:2003(R)2008, Sterilization of Health Care Products – Requirements for products labeled "Sterile".

The V-Go and EZ Fill have been tested as pyrogen free using USP <85> Bacterial Endotoxin Testing Gel Clot Method with an acceptable maximum limit of 20EU/device.

Packaging consists of a thermoformed plastic tray with a Tyvek heat sealable lidstock. Packaging validation demonstrated that the packaging can maintain sterility integrity for up to 36 months per AAMI/ISO 11607-1:2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems.

Drug Stability

Humalog has been tested in the V-Go and has been demonstrated to be stable for up to 24 hours storage followed by 24 hours wear. The EZ Fill has been demonstrated to be acceptable for filling Humalog for up to 30 days use.

Clinical Performance Data:

No clinical performance data is required to validate the intended uses and user needs of the system. Design validation is completed by human factors simulated use and clinical evaluation testing.

Conclusion:

Results of performance testing demonstrated substantial equivalence of the V-Go Disposable Insulin Delivery System to the predicate 510(k) device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Scott Huie
Vice President, Operations
Valeritas, LLC
800 Boston Turnpike
Shrewsbury, Massachusetts 01545

DEC 1 2010

Re: K100504
Trade/Device Name: V-Go™ 20 Disposable Insulin Delivery Device, V-Go™ 40 Disposable Insulin Delivery Device & V-Go™ 30 Disposable Insulin Delivery Device
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: November 19, 2010
Received: November 22, 2010

Dear Mr. Huie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

DEC 1 2010

510(k) Number (if known): K100504

Device Name: V-Go™ 40 Disposable Insulin Delivery Device

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/1/2010

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100504

4. Indications for Use Statement

510(k) Number (if known): K100504

Device Name: V-Go™ 30 Disposable Insulin Delivery Device

Indications For Use:

The V-Go 30 Disposable Insulin Delivery Device is indicated for continuous subcutaneous infusion of 30 Units of insulin in one 24-hour time period (1.25U/hr) and on-demand bolus dosing in 2-Unit increments (up to 36 Units per one 24-hour time period) in adult patients requiring insulin

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

12/1/2010

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100504

4. Indications for Use Statement

510(k) Number (if known): K100504

Device Name: V-Go™ 20 Disposable Insulin Delivery Device

Indications For Use:

The V-Go 20 Disposable Insulin Delivery Device is indicated for continuous subcutaneous infusion of 20 Units of insulin in one 24-hour time period (0.83U/hr) and on-demand bolus dosing in 2-Unit increments (up to 36 Units per one 24-hour time period) in adult patients requiring insulin

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 12/1/2010

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100504